



Docket No. 44657-AAA-PCT-US/JPW/GJG/DNS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Joseph R. Berger
Serial No.: 10/052,961 Group Art Unit: 1617
Filed : January 18, 2002 Examiner: Russell Travers
Title : A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING
IN A PATIENT INFECTED WITH HUMAN IMMUNODEFICIENCY
VIRUS-TYPE 1

1185 Avenue of the Americas
New York, New York 10036
May 14, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TO THE
ACCOMPANYING REQUEST FOR CONTINUED EXAMINATION (RCE) AND PETITION
FOR ONE MONTH EXTENSION OF TIME**

Applicants are filing this Third Supplemental Information Disclosure Statement and petition for a one-month extension of time to bring the subject application into pending status on the date of filing of the accompanying Request for Continued Examination. Specifically, a response to the January 14, 2004 Final Office Action was due April 14, 2004. Applicants hereby request a one-month extension of time. With a one-month extension of time, a response to the January 14, 2004 Final Office Action is due May 14, 2004. The fee for a one-month extension of time is \$55.00, and a check including this amount is enclosed. Therefore, a response to the January 14, 2004 Office Action is now due May 14, 2004 and the accompanying Request for Continued Examination is being timely filed.

Applicants are filing this Third Supplemental Information Disclosure Statement to supplement the Information Disclosure Statement filed on January 18, 2002, the Supplemental Information Disclosure Statement filed on October 9, 2003, and the Supplemental

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Information Disclosure Statement filed on March 5, 2004.

In accordance with their duty of disclosure under 37 C.F.R. § 1.56 and pursuant to § 1.97(b)(4), applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**) and attached hereto:

1. U.S. Patent No. 5,872,147, issued February 16, 1999, Bowen (**Exhibit 1**);
2. U.S. Patent No. 6,576,659, issued June 10, 2003, Fishbein (**Exhibit 2**);
3. U.S. Patent No. 6,670,351, issued December 30, 2003, Berger (**Exhibit 3**);
4. U.S. Patent Application Publication No. 2002/0091155, Published July 11, 2002, Berger (**Exhibit 4**);
5. U.S. Patent Application Publication No. 2003/0049716, Published March 13, 2003, Barton and Kramer. (**Exhibit 5**);
6. U.S. Serial No. 10/799,264, filed March 12, 2004, Fishbein (**Exhibit 6**);
7. U.S. Serial No. 10/799,197, filed March 12, 2004, Fishbein (**Exhibit 7**);
8. *Chicago Tribune*, (Sep. 20, 1991), North Sports Final edition, Business Section, page 1 (**Exhibit 8**);
9. Demling and DeSanti, (1997), "Oxandrolone, an Anabolic Steroid, Significantly Increases the Rate of Weight Gain In the Recovery Phase After Major Burns," *J. Trauma*, Vol. 43, No. 1, pp. 47-51 (**Exhibit 9**);

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10. Demling and De Santi, (October 1998), "Closure of the 'Non-Healing Wound' Corresponds with Correction of Weight Loss Using the Anabolic Agent Oxandrolone," *Ostomy/Wound Management*, Vol. 44, No. 10, pp. 58-60, 62, 64, ,66, 68 (**Exhibit 10**);
11. Demling, (1999), "Comparison of the Anabolic Effects and Complications of Human Growth Hormone and the Testosterone Analog, Oxandrolone, After Severe Burn Injury," *Burns*, Vol. 25, pp. 215-221 (**Exhibit 11**);
12. Demling, (Mar-Apr 2000), "Oxandrolone, an Anabolic Steroid, Enhances the Healing of a Cutaneous Wound in the Rat," *Wound Repair Regen.*, Vol. 8, No. 2, pp. 97-102 (**Exhibit 12**);
13. Demling and DeSanti, (2001), "The Rate of Restoration of Body Weight After Burn Injury, Using the Anabolic Agent Oxandrolone, is not Age Dependent," *Burns*, Vol. 17, pp. 46-51 (**Exhibit 13**);
14. Demling and DeSanti, (September/October 2001), "The Anabolic Steroid, Oxandrolone, Reverses the Wound Healing Impairment in Corticosteroid-Dependent Burn and Wound Patients," *Wounds*, Vol. 13, No. 5, pp. 203-207 (**Exhibit 14**);
15. DeSanti et al., (1998), "Development of a Burn Rehabilitation Unit: Impact on Burn Center Length of Stay and Functional Outcome," *Journal of Burn Care & Rehabilitation*, Vol. 19, No. 5, pp. 414-419 (**Exhibit 15**);
16. Ehrlich and Hunt, (August 1969), "The Effects of Cortisone and Anabolic Steroids on the Tensile Strength of Healing Wounds," *Ann Surg.*, Vol. 170, No. 2, pp. 203-206 (**Exhibit 16**);

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17. Eisenberg, (1966), 65 *Chemical Abstracts*:40387 (**Exhibit 17**);
18. Eisenberg, (May 1966), "Effects of Androgens, Estrogens and Corticoids on Strontium Kinetics in Man," *J. Clin. Endocr.*, Vol. 26, pp. 566-572 (**Exhibit 18**);
19. Ferraresi, (April 1996), "Clinical Profile of Oxandrin," BTG Pharmaceuticals (**Exhibit 19**);
20. Grant, (1980), "Patient Selection," in *Handbook of Total Parenteral Nutrition*, Saunders, pp. 7-46 (**Exhibit 20**);
21. Hausmann et al., (March/April 1990), "Anabolic Steroids In Polytrauma Patients. Influence on Renal Nitrogen and Amino Acid Losses: A Double Blind Study," *J. Parent. Enteral. Nutr.*, Vol. 14, No. 2, pp. 111-114 (**Exhibit 21**);
22. Helfman and Falanga, (August 1995), "Stanozolol as a Novel Therapeutic Agent in Dermatology," *J. of the American Acad. of Dermatology*, Vol. 33, No. 2, pp. 254-258 (**Exhibit 22**);
23. Jekot and Purdy, (April 1993), "Treating HIV/AIDS Patients with Anabolic Steroids," *AIDS Patient Care*, pp. 68-74 (**Exhibit 23**);
24. Koehler et al., (1998), "Achieving Healing of 'Non-Healing Pressure Ulcers," 1998 WOCN 30th Annual Conference, p. 37 (**Exhibit 24**);
25. Kotler, (1996), "Dilemmas in the Treatment of Weight Loss," BTG Pharmaceuticals, pp. 1-7 (**Exhibit 25**);
26. Levien et al., (July 1994), "Reviews of Trimetrexate and Oxandrolone," *Hospital Pharmacy*, Vol. 29, No. 7, pp. 696-702, 705-708 (**Exhibit 26**);

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27. Martindale, (1982), *The Extra Pharmacopoeia 28th edition*, The Pharmaceutical Press, London, Reynolds and Prasad Eds., p. 1430 (**Exhibit 27**);
28. PR Newswire, 0828P8715, (August 28, 1991), "Gynex Obtains International Rights to Drug to Treat For Growth Disorders, AIDS" (**Exhibit 28**);
29. Schwartz and Miller, (1986), "Androgens and Anabolic Steroids," in *Modern Pharmacology, Second Edition*, Little Brown and Company, Boston/Toronto, Craig and Stitzel Eds., pp. 905-924 (**Exhibit 29**);
30. Tennenbaum and Shklar, (December 1970), "The Effect of an Anabolic Steroid on the Healing of Experimental Extraction Wounds," *Oral Surg.*, Vol. 30, No. 6, pp. 824-834 (**Exhibit 30**); and
31. Udupa and Chansouria, (March 1969), "Studies on Wound Healing," *Indian J. Med. Res.*, Vol. 57, pp. 434-456 (**Exhibit 31**).

This Third Supplemental Information Disclosure Statement accompanies a Request for Continued Examination ("RCE") of U.S. Serial No. 10/052,961, filed January 18, 2002. A Final Office Action was issued January 14, 2004 in connection with the U.S. Serial No. 10/052,961, to which a response is due April 14, 2004. Accordingly, this RCE is timely filed.

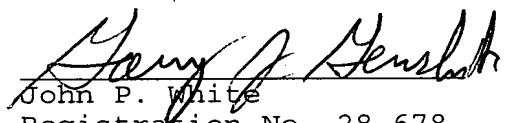
No fee, other than the RCE fee of \$385.00 and the fee of \$55.00 for a One-Month Extension of time, both enclosed on the check for \$440.00, is deemed necessary in connection with the filing of this Third Supplemental Information Disclosure Statement. If any such fee is required, authorization is hereby given to charge the amount

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of any such fee to Deposit Account No. 03-3125.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Respectfully submitted,



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Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeINFORMATION DISCLOSURE CITATION
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Atty. Docket No. 44657-AAA-PCT-US | Serial No. 10/052,961

Applicant:
Joseph R. BergerFiling Date
January 18, 2002 | Group

U.S. PATENT DOCUMENTS

Examiner Initial		Document Number							Date	Name	Class	Subclass	Filing Date if Appropriate
US	5	8	7	2	1	4	7		2/16/99	Bowen			
US	6	5	7	6	6	5	9		6/10/03	Fishbein			
US	6	6	7	0	3	5	1		12/30/03	Berger			

FOREIGN PATENT DOCUMENTS

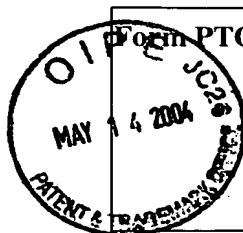
		Document Number							Date	Country	Class	Subclass	Translation		
														Yes	No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

· U.S. Published Application No. 2002/0091155, Published July 11, 2002, Berger (Exhibit 4);
· U.S. Published Application No. 2003/0049716, Published March 13, 2003, Barton and Kramer. (Exhibit 5);
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EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form PTO-1449

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FOREIGN PATENT DOCUMENTS

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						Yes
						No

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Hausmann et al., (March/April 1990), "Anabolic Steroids In Polytrauma Patients. Influence on Renal Nitrogen and Amino Acid Losses: A Double Blind Study," <i>J. Parent. Enteral. Nutr.</i> , Vol. 14, No. 2, pp. 111-114 (Exhibit 21);
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